

Remarks

Claims 1-4 are pending in the present application. Claims 1-4 are rejected under 35 USC 102(a) and under 35 USC 103(a).

The Examiner's rejections shall now be addressed in the order that they were made.

Rejection of Claims 1-4 Under 35 USC 102(a)

The Examiner has rejected Claims 1-4 as being anticipated by Singer *et al.*, which, presumably refers to US Patent No. 6,365,574. Specifically, the Examiner stated that Singer *et al.* disclose the claimed ethanolate of azithromycin in the form of powder and suspensions for oral administration.

The Examiner is correct that Singer *et al.* disclose an ethanolate of azithromycin and also states that suitable oral forms of pharmaceutical compositions, containing this ethanolate of azithromycin, include tablets, compressed or coated pills, dragees, sachets of powder for reconstitution, hard or gelatin capsules, sub-lingual tablets, syrups and suspensions.

However, the invention recited in Claims 1-4 of the present Application recite a powder for oral suspension, and an oral suspension, comprising a n-propanol solvate of non-dihydrate azithromycin rather than the ethanolate of azithromycin disclosed by Singer *et al.*

Therefore, Claims 1-4 of the present Application are not anticipated by Singer *et al.*

Rejection of Claims 1-4 Under 35 USC 103(a)

The Examiner has rejected Claims 1-4 as being obvious over US Patent No. 6,245,903 (hereinafter "Karimian *et al.*") in combination with US Patent No. 6,365,573 (hereinafter "Singer *et al.*"). Specifically, the Examiner stated that Karimian *et al.* disclose that azithromycin monohydrate isopropanol clatharate may be used in formulations of the drug product as tablets or capsules but do not disclose azithromycin monohydrate isopropanol clatharate in the form of a powder for oral suspension. The Examiner also stated that Singer *et al.* disclose a loosely analogous ethanolate of azithromycin in the form of powder and suspensions. The Examiner concluded that a person of ordinary skill in the art would have been motivated to prepare the compound of

Karimian *et al.* (azithromycin monohydrate isopropanol clatharate) in the form of a powder for oral suspension.

Contrary to the Examiner's statements, the powder for oral suspension and oral suspension of the present invention are neither disclosed nor suggested by the teachings of Karimian *et al.* and Singer *et al.* taken either separately or in combination.

Claims 1-4 of the present Application recite a powder for oral suspension, and an oral suspension, comprising a n-propanol solvate of non-dihydrate azithromycin. Neither Karimian *et al.* nor Singer *et al.* either disclose or suggest a n-propanol solvate of non-dihydrate azithromycin. Rather, Karimian *et al.* discloses azithromycin monohydrate isopropanol clatharate. Isopropanol and n-propanol are different compounds. Further, Singer *et al.* discloses an ethanolate of azithromycin.

Therefore, Claims 1-4 are not obvious over Karimian *et al.* in combination of Singer *et al.*

Conclusion

In view of the above, Applicant respectfully requests that the Examiner's rejections of Claims 1-4 under 35 USC 102(a) and 35 USC 103(a), for the reasons cited above, should be withdrawn. Applicant further requests that a notice of allowance be issued for pending Claims 1-4.

Respectfully Submitted:

Date: 29 September 2004



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